REMARKS

Claims 1 to 5 are pending. Claims 6 to 13 have been previously withdrawn by election in response to a restriction requirement.

The specification is herein amended in accordance with the request of the Examiner.

Claims 1 and 5 are herein amended. Support for amendment of claims 1 and 5 may be found throughout the application. For example, at paragraph 8, Applicant teaches the use of Recognins in aid of other treatment: "The present invention describes products to aid both cancer prevention and cancer treatment." (all citations herein are to the Substitute Specification filed July 27, 2001). Support is further found, for example, at paragraph 12, which discloses anti-Recognin as an inhibitory agent that may be augmented in immune stimulation of humans: "Taken together, these properties suggest that anti-Recognin is a general inhibitory transformation antibody whose augmentation may be useful in efforts at the immune prevention and treatment of cancer."

Further, Applicant teaches at paragraph 2 that the present invention is directed at strengthening the immune system by stimulating, *inter alia*, "the cellular part of the immune response." Support may also be found at paragraph 34 where Applicant teaches: "[Recognin derivatives] can be administered as vaccine to individual humans or animals, for example, but not exclusively, in doses approximately 1 mg or more subcutaneously . . . ."

Even further support is found at paragraph 28 where Applicant teaches that administration of Recognin stimulates the cellular and humoral elements and can be useful in augmenting cancer therapy:

> [T]he present demonstration that anti-Recognin is cytotoxic and inhibitory to cancer cells, and that some but not all sites on cancer cells *in vivo* are covered by anti-Recognin, together indicate that an effort to augment this inhibitory antibody by administering the human antibody itself, or a derivative of a Recognin (a derivative of malignin, Recognin L or Recognin M) as vaccine to stimulate both the cellular and humoral elements, can be useful in efforts at the immune prevention and therapy of cancer.

A review of the application, therefore, would provide the skilled artisan with a firm appreciation that Applicant possessed, at the time of filing, processes and compositions for

stimulating the immune system of a subject wherein the process does not by itself protect against or treat cancer but, instead, augments therapy.

A. THE FILING DATE

The Examiner has indicated that there is confusion about the lineage of the instant application. The specification has been amended to correct the lineage. The priority claim has been clarified in the replacement paragraph to indicate the instant application claims priority only to U.S. Pat. Appln. Ser. No. 08/031,562, filed March 16, 1993, and U.S. Pat. Appln. Ser. No. 07/744,649, filed August 8, 1991. Accordingly, Applicant respectfully requests withdrawal of this ground of objection.

B. THE SPECIFICATION

The Examiner has objected to the specification for various informalities. Specifically, the lineage of applications. The present amendment to the specification has addressed these informalities. Accordingly, Applicant requests withdrawal of this ground of objection.

C. EXAMINER NOTES CURRENT DRAWINGS NOT IN COLOR

The Examiner has noted that in the parent application, U.S. Pat. Appln. Ser. No. 08/031,562, Figure 1 is in color; while in the current application, the drawings are not in color. It does not appear that the Examiner has objected to the drawings. At this time, Applicant does not wish to submit drawings in color. Should the Examiner prefer Figure 1 in color, or if the current drawings are objected to, Applicant will gladly provide such figure with the requisite petition and fee or will file new formal drawings.

D. THE DECLARATION

The Examiner has indicated that the declaration is defective. Applicant submits herewith a new declaration, signed by the inventor, which indicates that the present application claims priority to U.S. Pat. Appln. Ser. No. 08/031,562, filed Mar. 16, 1993, and U.S. Pat. Appln. Ser. No. 07/744,649, filed Aug. 8, 1991. Applicant, therefore, respectfully requests this ground of objection be withdrawn.

E. REJECTION OF CLAIMS 1 TO 5 UNDER 35 U.S.C. § 112, PARAGRAPH 2—Definiteness

The Examiner has rejected claims 1 to 5 under 35 U.S.C. § 112, second paragraph, for indefiniteness. The Examiner asserts U.S. Pat. No. 4,976,957 "teaches that 'Recognin' is a genus having the species astrocytin, Malignin, Recognin M and Recognin L" while the Examiner

considers the claims of the application to "indicat[e] that 'malignin' is a genus having the species malignin, recognin M, and recognin L." Applicant respectfully requests the Examiner withdraw this rejection.

Contrary to the Examiner's assertion, Applicant respectfully urges the claims do not suggest malignin is a genus. Instead, the application teaches that malignin, Recognin M and Recognin L share immunological specificity, *i.e.*, "[t]he Recognin derivative . . . contains the immunological specificity of malignin, Recognin L or Recognin M." Appln. at ¶ 29. Since these compounds share immunological specificity, they are interchangeable within the claimed process or composition. No particular listed compound represents a genus that defines the others. Instead, each compound is equally effective as an element in the claims. There is nothing indefinite in a list of compounds that are interchangeable. Because the listing of compounds in the claims is related to shared immunological specificity as taught in the specification, Applicant respectfully requests withdrawal of this rejection.

F. REJECTION OF CLAIMS 1 TO 5 UNDER 35 U.S.C. § 112, PARAGRAPH 1—Enablement

1. Enablement rejection for new matter

The Examiner has rejected claims 1 to 5 under 35 U.S.C. § 112, first paragraph, for failure to comply with the enablement requirement because "[t]he claim language 'stimulating the immune system of a subject to produce and release antimalignin antibody' is new matter." Applicant respectfully traverses the Examiner's rejection because throughout the application, Applicant teaches the stimulation of the immune system to produce and release antimalignin antibody.

For example, at page two of the application (and at page two of the parent application, U.S. Appln. Ser. No. 08/031,562) Applicant teaches "administration of . . . a derivative of a Recognin, to produce both the antibody and the cellular part of the immune response . . . ." One of skill in the art would understand "stimulating the immune system of a subject to produce and release antimalignin antibody" to be equivalent with "produc[ing] both the antibody and the cellular part of the immune response" since these sentences encompass both the element of (1) an immune response and (2) antibody production. One of skill in the art would recognize that the language of the claims comports with the language of the applications; and would consider the subject matter of claims 1 to 5 fully supported in the applications as filed.

In rejecting claims 1 to 5 for new matter, the Examiner additionally avers that the original specification does not contain an abstract. Applicant's records, as evidenced by a postcard indicating that 22 pages of specification were filed and received at the USPTO, show an abstract was filed with the original application on May 15, 2001 at page 22. A copy of the postcard and the originally filed page 22 (Abstract) are enclosed herewith. Applicant additionally filed the identical abstract with the Substitute Specification on July 27, 2001 as page 17. A copy of the Substitute Specification, filed on July 27, 2001, is enclosed herewith for the Examiner's convenience.

2. Enablement rejection for prevention of cancer and vaccines to cancer

The Examiner has also rejected claims 1 to 5 for lack of enablement. The Examiner asserts that the claims encompass prevention of cancer, including vaccines to cancer. Although the claims do not recite treatment of cancer or vaccination for cancer, the Examiner argues that vaccination and treatment are "the only embodiment[s] or utility disclosed" and the claims must enable vaccination and prevention of cancer.

Applicant has amended independent claims 1 and 5. The current amendments should obviate the Examiner's rejection. The Examiner has stated: "[A] 'vaccine' must protect the vaccinated patient from a specific disease." In response to the Examiner's statement, Applicant has amended the claims to indicate that the processes and compositions of the claims do not by themselves protect against or treat cancer.

The claims, as amended, are not directed to "a cure for cancer" and do no purport to alone protect against or treat cancer. Instead, they are directed to assisting the body in conjunction with other therapies by administering malignins to "stimulate the immune system." The fact that the stimulation of the immune system causes production of anti-malignin antibodies indicates that stimulation of the immune system has indeed occurred.

Although not wishing to be bound by theory, the specification suggests "anti-Recognin is a general inhibitory transformation antibody whose augmentation may be useful in efforts at the immune prevention and treatment of cancer." Appln. at ¶ [0012]. The skilled artisan would understand that the plural "efforts" of paragraph 12 are not restricted to the presence of anti-malignin antibody alone but to its presence in conjunction with other efforts.

Furthermore, the specification teaches that the anti-malignin antibody is present in healthy individuals and rises with increase in cancer risk and presence of cancer, *see* Appln. at ¶

[0005], and that increases in concentration of the anti-malignin antibody are correlated with survival in cancer patients. *See* Appln. at ¶ [0009]. The artisan would understand from these data and the instructions of the specification that "[t]he present invention describes products[, namely malignins,] to aid both cancer prevention and cancer treatment." Appln. at ¶ [0008].

Moreover, it was known in the art at the time of filing that products that aid the immune response can be very important in assisting the total immune response to an antigen of interest. The artisan would have understood, on review of the application, that augmentation of the immune response to an antigen is sometimes as important as presenting the antigen itself to the immune system.

The specification fully describes to one of skill in the art how to stimulate the immune system with malignin to assist in cancer treatment or conventional cancer therapy. As such, the claims are enabled. Accordingly, Applicant respectfully requests withdrawal of the present rejection of the claims for lack of enablement.

G. REJECTION OF CLAIMS 1 TO 5 UNDER 35 U.S.C. § 102(b)—Anticipation

Claims 1 to 5 have been rejected as anticipated over U.S. Pat. No. 4,976,957 to Bogoch and claims 1 to 3 and 5 have been rejected as anticipated over EP 0,015,078 to Bogoch. The Examiner asserts the patents "teach preparations of malignin, Recognin-M or recognin-L for the immunization of animals, in order to produce antibodies thereto." The claims, as amended, are not directed to immunization. Furthermore, Applicant submits U.S. Pat. No. 4,976,957 and EP 0,015,078 do not teach or suggest "stimulating the immune system of a subject to produce and release antimalignin antibody [by] administering to the subject an effective amount of a first dosage of . . . malignin, recognin M, [or] Recognin L . . . which process does not by itself protect against or treat cancer." Accordingly, Applicant respectfully requests the current rejection be withdrawn.

H. REJECTION OF CLAIM 1, 3 AND 4 UNDER 35 U.S.C. § 103(a)—Obviousness

Claims 1, 3 and 4 have been rejected over Bogoch (US '957 and EP '078) in view of Chase. The Examiner asserts "Chase shows a variety of immunization regimens." However, as stated above, Applicant submits U.S. Pat. No. 4,976,957 and EP 0,015,078 do not teach or suggest "stimulating the immune system of a subject to produce and release antimalignin antibody [by] administering to the subject an effective amount of a first dosage of . . . malignin, recognin M [or] Recognin L . . . which process does not by itself protect against or treat cancer." Furthermore, the claims as amended are not directed at immunization and, as a result, render

Chase inapposite. Accordingly, Applicant respectfully requests the current rejection be withdrawn.

CONCLUSION

It is believed that the present claims are in conditions for allowance and Applicant earnestly requests allowance. Extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required therefor are hereby authorized to be charged to our Deposit Account No. 11-0600. The Examiner is invited to contact the undersigned attorney if necessary to expedite allowance.

An early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

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